

Claims

1. A process for preparing a stable granulate for reconstitution with water into an oral aqueous suspension comprising amoxicillin trihydrate and a sugar, the process comprising the following steps:
 - a. sieving the mixture of amoxicillin trihydrate and the sugar
 - b. extruding said sieved mixture with water or aqueous solution of the sugar as granulation liquid to obtain a wet extruded mass
 - c. screening the wet extruded mass through a sieve
 - d. drying the sieved wet extruded mass
 - e. dried and sieved extruded mass is homogenized to the granulate
 - f. obtained granulate is dissolved in water to form smooth suspension immediately.
2. A process according to claim 1, wherein the sugar is selected from the group consisting of sucrose, lactose, sugar alcohols and maltodextrins alone or in combination.
3. A process according to claim 1, wherein the sugar is sucrose.
4. A process according to claim 2, wherein the sugar alcohol is manitol or sorbitol.
5. A process according to claim 1, wherein amoxicillin trihydrate is present in from 1 to 80% by weight of the granulate.
6. A process according to claim 1, wherein amoxicillin trihydrate is present in from 5 to 50% by weight of the granulate.
7. A process according to claim 1, wherein amoxicillin trihydrate is present in from 10 to 30% by weight of the granulate.

8. A process according to claims 1 to 3, wherein sucrose is present in from 20 to 99% by weight of the granulate.
9. A process according to any one of claims 1 to 8, wherein the particle size of the granulate is in the range from 200 to 3000 μm .
10. A process according to claim 9, wherein the particle size of the granulate is in the range from 500 to 1500 μm .
11. A process according to any of claims 1 to 10, wherein no pharmaceutically acceptable excipient is added during the process.
12. A process as claimed in any of claims 1 to 10, wherein optionally pharmaceutically acceptable excipient is added during the process.
13. A process for preparing free flowing granulate for filling into glass bottles, unit dose sachets or into other suitable container, used for reconstitution into an aqueous suspension, which process comprises preparing granulates according to any one of the preceding claims.
14. A granulate comprising amoxicillin trihydrate and a sugar.
15. A granulate according to claim 14 for reconstitution into an aqueous suspension.
16. A granulate according to claims 14 to 15, wherein the sugar is selected from the group consisting of sucrose, lactose, sugar alcohols and maltodextrins alone or in combination.
17. A granulate according to claims 14 to 15, wherein the sugar is sucrose.

18. A granulate according to claims 14 to 16, wherein the sugar alcohol is manitol or sorbitol.
19. A granulate according to claims 14 to 18, wherein amoxycillin trihydrate is present in from 1 to 80% by weight of the granulate.
20. A granulate according to claims 14 to 18, wherein amoxicillin trihydrate is present in from 5 to 50% by weight of the granulate.
21. A granulate according to claims 14 to 18, wherein amoxicillin trihydrate is present in from 10 to 30% by weight of the granulate.
22. A granulate according to claims 14 to 17, wherein sucrose is present in from 20 to 99% by weight of the granulate.
23. A granulate according to claims 14 to 17, wherein sucrose is present in from 70 to 90% by weight of the granulate.
24. A granulate according to any one of claims 14 to 23, wherein the particle size of a granulate is in the range of 200 to 3000 μm .
25. A granulate according to any one of claims 14 to 24, wherein the particle size of the granulate is in the range of 500 to 1500 μm .
26. A granulate according to claims 14 to 25, wherein the granulate contain no pharmaceutically acceptable excipient.
27. A granulate according to claims 14 to 25, wherein the granulate optionally contain pharmaceutically acceptable excipient.

28. A granulate according to claims 14 to 27, which is free flowing and which is provided in glass bottles, unit dose sachets or in other suitable container.
29. A granulate comprising amoxicillin trihydrate and the sugar according to any one of claims 14 to 28, wherein the granulate is reconstituted with water into an aqueous suspension which can be swallowed by a patient.
30. A granulate comprising amoxicillin trihydrate and the sugar, free of any pharmaceutically acceptable excipient.
31. A granulate according to claims 14 to 30, provided for pediatric use which is reconstituted with water into an aqueous suspension prior to use.
32. An aqueous suspension for oral administration to humans or animals comprising amoxicillin trihydrate and the sugar obtained after reconstitution of the granulate, prepared according to claims 1 to 13, with water into the aqueous solution.
33. A sachet product containing free flowing granulate according to claims 14 to 30, which comprises amoxicillin trihydrate and the sugar in a suitable unit dose, for reconstitution with water into an aqueous suspension immediately prior to use.
34. A method of treatment of bacterial infections in humans or animals, which comprises the administration of the granulate comprising therapeutically effective amount of amoxicillin trihydrate and the sugar.
35. The use of granulate comprising amoxicillin trihydrate and the sugar according to claims 14 to 30 in the manufacture of a medicament for treating bacterial infections.